FDA 510(k) Premarket Notification

K222304 Sonata Transcervical Fibroid Ablation System 2.2

CLEARED

Nov 8, 2022
99 days to decision

K222304 · Product code: **KNF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k222304/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coagulator-cutter, Endoscopic, Unipolar (and Accessories) (KNF)
Date received	Aug 1, 2022
Decision date	Nov 8, 2022
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Gynesonics, Inc.**
Location	Redwood City, CA, US
Contact	Diane King
510(k) history	8 submissions · 8 cleared · 2006-2025